

Short- and intermediate-term improvement of patient quality of life after transcatheter aortic valve implantation: a single-centre study

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Abstract

Background: Transcatheter aortic valve implantation (TAVI) is a treatment option for elderly high-risk patients with symptomatic severe aortic stenosis. Improvement of quality of life (QoL) is a relevant issue in this group of patients.

Aim: To assess changes in QoL after TAVI.

Methods: Forty patients who underwent TAVI in our institution were included in this QoL study. All subjects were screened for TAVI in a standard fashion, including QoL assessment with the EQoL (EQ-5D-3L). The pre- and postprocedural scores obtained up to a 12-month follow-up were assessed.

Results: Median of logistic EuroScore I was 21.5% (13.5–26.75%), and Society of Thoracic Surgeons score was 5.5% (4.0–10.75%). Comparison of baseline values with follow-up data at one, six and 12 months after TAVI showed significant improvement of QoL ($p < 0.001$). Visual Analogue Scale score (VAS score) was assessed. There was an incremental increase in VAS score during follow-up ($p < 0.001$). Median of six-minute walk test distance at baseline was 200 m (IQR 150–300) and 325 m (IQR 250–400) 12 months after TAVI ($p < 0.001$).

Conclusions: TAVI provides improved QoL and effectively relieves symptoms.

Key words: aortic stenosis, TAVI, elderly, quality of life

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a relatively modern and less invasive treatment option for elderly, high risk patients with symptomatic severe aortic stenosis (AS) than surgical aortic valve replacement (AVR). TAVI improves survival compared to conservative treatment in patients who are not suitable for surgical AVR [1] and is non-inferior to AVR regarding survival in selected patients [2]. TAVI mends not only major cardiovascular and cerebrovascular events [3–7], but also ameliorates symptoms such as dyspnoea, angina and fatigue and therefore influences quality of life (QoL) [8]. Also, QoL assessment is a part of the Valve Academic Research Consortium definitions [9] thus an important parameter in the assessment of procedure outcomes. The purpose of the present study was to evaluate the changes

of QoL in consecutive high-surgical-risk patients up to 12 months after TAVI.

METHODS

Patients

Initially, 55 high risk patients with severe symptomatic AS underwent TAVI in our institution, but finally the data from 40 patients was analysed. All patients were evaluated by a dedicated multidisciplinary Heart Team [10]. Preprocedural assessment included transthoracic and transoesophageal echocardiography, carotid ultrasonography, spirometry, coronary angiogram, and evaluation of peripheral access sites by arterial angiography and/or computed tomography angiography. Clinical decision-making was based on a multimodality screening assessment including evaluation of surgical risk by

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logistic EuroScore I > 20% or Society of Thoracic Surgeons score > 10%. Additional risk criteria were porcelain aorta, advanced liver cirrhosis, severe neurological impairment, and frailty due to physician judgment.

Procedure

For a transfemoral (TF) approach, vascular access was obtained by puncture of the common femoral artery under fluoroscopic guidance. After insertion of the delivery sheath, TAVI was performed using either the Medtronic CoreValve (Medtronic, Inc., Minneapolis, MN, USA) or the Edwards Sapien Transcatheter Heart Valve (Edwards Lifesciences, Irvine, CA, USA). For a transapical (TA) approach, the apex of the heart was punctured under ultrasound guidance. Most procedures were performed under general anaesthesia with transoesophageal echocardiographic guidance.

Quality of life assessment

QoL was assessed with the validated Polish version of the EQ-5D-3L questionnaire at baseline, one, six and 12 months after TAVI. EQ-5D is a standardised measure of health status developed by the EuroQol group (permission granted) in order to provide a simple, generic measure of health for clinical and economic appraisal [11]. Visual Analogue Scale (VAS) score which is a part of EQ-5D-3L was also assessed. Additionally a six-minute walk test distance was assessed at baseline and at 12 months after TAVI.

Statistical analysis

Results were presented as numbers of patients (percentages) or median (interquartile range [IQR]) where applicable. Changes in categories of EQ-5D-3L questionnaire between baseline and follow-up assessments were tested using χ^2 test. Differences in the VAS score and six-minute walk test distance between baseline and follow-up assessments were analysed with a Wilcoxon signed-rank test. All tests were two-tailed, and a p value < 0.05 was considered statistically significant. All statistical analysis was performed using SPSS 15.0 (SPSS, Inc., Chicago, IL, USA).

RESULTS

Baseline patient demographics are presented in Table 1. Values are presented as percentages or median (IQR). Thirty three procedures were performed under general anaesthesia, and seven procedures in analgosedation. An Edwards Sapien prosthesis was implanted in 30 patients (14 TF and 16 TA) and a CoreValve was implanted in ten patients (all TF). The median hospital stay was seven days. At follow-up, all patients underwent clinical evaluation and transthoracic echocardiography assessment.

Forty patients were included in the QoL study. At baseline, patients with AS presented with major impairment in

Table 1. Baseline characteristics and parameters before TAVI

Variable	N = 40
Age [years]	80.5 (76.25–83.0)
Age ≥ 75 years	79.2%
Men	33.3%
Body mass index [kg/m ²]	25.0 (26.0–27.75)
Arterial hypertension	91.7%
Diabetes mellitus	20.8%
Hyperlipidaemia	70.8%
Current smoker	0.0%
Previous MI	37.5%
Previous PCI	33.4%
Previous CABG	25.0%
Chronic kidney disease	25.0%
Atrial fibrillation	25.0%
Symptoms:	
Canadian Cardiovascular Society	
I	13.6%
II	72.7%
III + IV	13.5%
New York Heart Association	
I	0.0%
II	8.4%
III + IV	91.6%
Previous syncope	29.2%
Aortic valve parameters:	
PG max [mm Hg]	94.0 (85.0–128.25)
PG mean [mm Hg]	56 (50.0–73.75)
Aortic valve area [cm ²]	0.6 (0.45–0.7)
LVEF [%]	60.0 (46.0–65.0)
Risk of surgery	
Logistic EuroScore I [%]	21.5 (13.5–26.75)
Society of Thoracic Surgeons score [%]	5.5 (4.0–10.75)

TAVI — transcatheter aortic valve implantation; MI — myocardial infarction; PCI — percutaneous coronary intervention; CABG — coronary artery bypass grafting; PG — pressure gradient; LVEF — left ventricular ejection fraction

physical status. A comparison of baseline values to follow-up data at one, six and 12 months after TAVI showed a significant improvement of QoL (Figs. 1A–E; $p < 0.001$). VAS score results are presented in Figure 2. There was an incremental increase in VAS score during follow-up ($p < 0.001$). We also compared QoL data among TF and TA patients, but no significant correlation was found. Median of six-minute walk test distance at baseline was 200 m (IQR 150–300) and 325 m (IQR 250–400) 12 months after TAVI ($p < 0.001$). All-cause mortality rate was 14.5% at 12 months among 55 patients.

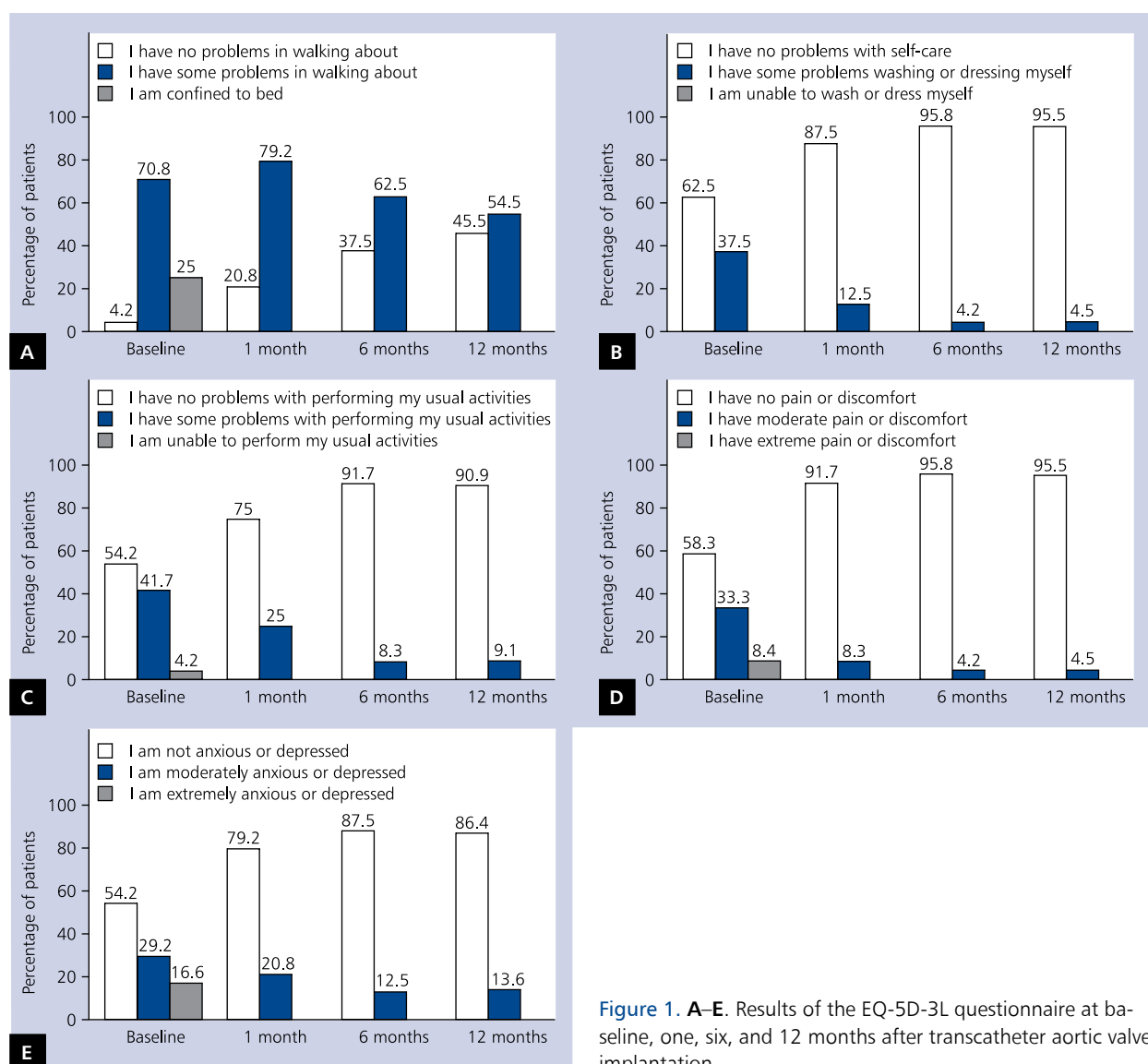


Figure 1. A–E. Results of the EQ-5D-3L questionnaire at baseline, one, six, and 12 months after transcatheter aortic valve implantation

DISCUSSION

The data presented in our study shows that most TAVI patients benefit from an improved QoL, which is sustained up to 12 months after the procedure. These results support the indication for TAVI in patients scheduled for optimal medical treatment because of advanced age or multiple comorbidities contributing to perioperative risk. However, QoL in the elderly is the result of multiple factors, including cardiac and non-cardiac comorbidities (e.g. obesity or joint degeneration). Most of these factors are not related to AS. TAVI is a less invasive technique and shortens the recovery time compared to surgical AVR. As a result, early improvement of symptoms and QoL have been reported previously compared to surgical patients [12, 13]. A QoL improvement in high-risk patients one year following TAVI has been previously reported [14–17]. The results of the PARTNER B cohort demonstrated that inoperable patients with severe AS, compared to standard care (medical

treatment and balloon aortic valvuloplasty), who underwent TAVI resulted in significant improvements in health-related QoL that were maintained for at least one year [18]. Several studies have compared health status and QoL outcomes for patients with severe AS and high surgical risk treated with either TAVI or AVR. Reynolds et al. [19] evaluated the health status of 628 patients in the PARTNER trial using the Kansas City Cardiomyopathy Questionnaire summary score which improved more with TAVI but was similar for the two groups at six and 12 months. However, there was a significant interaction between the benefit of TAVI and access site (TA vs. TF). Patients treated with the TF approach presented more health status benefits with TAVI vs. AVR at one month (difference 9.9 points, 95% CI 4.9–14.9, $p < 0.001$), whereas patients treated via the TA approach demonstrated no benefits with TAVI compared to AVR at any time point. In our study, we did not find any significant correlation among TF and TA patients.

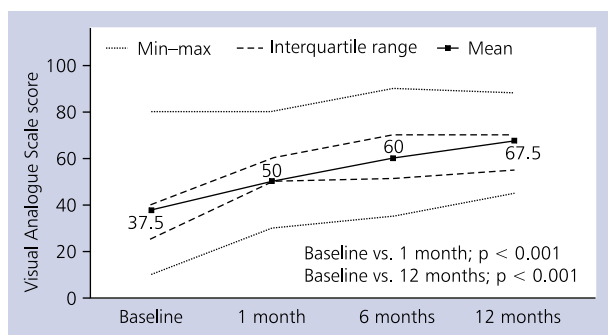


Figure 2. Visual Analogue Scale score of EQ-5D-3L at baseline, one, six, and 12 months after transcatheter aortic valve implantation; $p < 0.001$ for all comparisons (χ^2 test)

In our study, the QoL was assessed by the EQ-5D-3L questionnaire and a significant improvement was observed in health status. Initially we tried to assess the QoL with the SF-36 questionnaire, but only a few patients were able to answer the questions appropriately, and a majority had problems with answering.

Limitations of the study

This study is based on a single-centre experience with a low number of patients who have been treated with different devices (Edwards Sapien, Edwards Sapien XT, Medtronic CoreValve). Of 55 patients treated with TAVI, eight patients died before the 12-month follow-up. Five patients had only a six-month observation, and two patients did not sign the informed consent. The final number of patients analysed was 40. Other limitations of the present study are a non-randomised study design and the lack of a control group.

CONCLUSIONS

The improvement of QoL after TAVI in high risk patients with severe AS has been demonstrated using the EQ-5D-3L questionnaire.

Conflict of interest: none declared

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Poprawa jakości życia u chorych poddanych przezcewnikowej implantacji zastawki aortalnej: badanie jednośrodkowe

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Streszczenie

Wstęp: Przezcewnikowa implantacja zastawki aortalnej (TAVI) jest metodą leczenia starszych chorych z grupy wysokiego ryzyka z ciężką stenozą aortalną. Polepszenie jakości życia jest ważnym zagadnieniem w tej grupie pacjentów.

Cel: Celem badania była ocena jakości życia u chorych poddanych TAVI.

Metody: Zabiegowi TAVI poddano 55 kolejnych chorych, u 40 z nich wykonano ocenę jakości życia. Wszyscy pacjenci byli kwalifikowani do TAVI w sposób typowy, łącznie z oceną jakości życia za pomocą kwestionariusza EQoL (EQ-5D-3L). Wyniki uzyskano w obserwacji do 12. miesiąca po zabiegu.

Wyniki: Mediana (IQR) maksymalnego i średniego gradientu przez zastawkę aortalną wyniosła odpowiednio 94 mm Hg (85–128,25) i 56 mm Hg (50,0–73,75), pole powierzchni zastawki — 0,6 cm² (0,45–0,7). Mediana skali ryzyka logistic Euro-Score I wyniosła 21,5% (13,5–26,75), a STS — 5,5% (4,0–10,75). Wykazano istotne różnice w jakości życia w ocenie wyjściowej oraz po 1, 6 i 12 miesiącach po TAVI. Oceniano również skalę VAS i stwierdzono istotny wzrost punktacji ($p < 0,001$). Mediana odległości w teście 6-minutowego marszu wyniosła wyjściowo 200 m (IQR 150–300) i 325 m ((IQR 250–400) po 12 miesiącach po TAVI ($p < 0,001$).

Wnioski: TAVI zapewnia poprawę jakości życia i redukuje nasilenie objawów związanych z chorobą.

Słowa kluczowe: stenoza aortalna, TAVI, osoby starsze, jakość życia

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